

EPA R.E.D. FACTS

Lindane

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency assesses the risk associated with the use of the pesticide, and develops mitigation measures or regulatory controls to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for the reregistration of lindane.

Use Profile

Lindane is an organochlorine insecticide used as a pre-plant seed treatment for barley, corn, oats, rye, sorghum, and wheat. The pesticide is formulated into dust, emulsifiable concentrate, flowable concentrate, and liquid ready-to-use products. Lindane is applied to seeds using the following equipment: liquid seed treater, planter/seed box, air seed treater, canister tube applicator, and slurry-type seed treater. Approximately 233,000 lbs of active ingredient of lindane are used annually for seed treatment.

Lindane is also currently approved by the U.S. Food and Drug Administration (FDA) for use in pharmaceutical products intended to control head lice and scabies (mites) in humans.

Regulatory History

Lindane was first registered as a pesticide in the U.S. in the 1940's for use on a wide variety of food crops, ornamentals, livestock, homeowner, and other sites. In 1977, EPA initiated for lindane a Rebuttable Presumption Against Registration (RPAR) review, now called a Special Review. The lindane RPAR

was triggered based on questions of oncogenicity, fetotoxicity/ teratogenicity, reproductive effects, its potential to cause blood dyscrasias, and acute toxicity to wildlife. EPA published Position Documents (PDs) in 1977 through 1983, resulting in the cancellation of certain uses of lindane.

EPA issued a Registration Standard for lindane in September 1985, which included a Data Call-In (DCI) requiring submission of additional data to support the lindane registration and address exposure concerns from treated structures and animals. After issuance of the 1985 Registration Standard, many of the registered uses of lindane were cancelled, resulting in only seed treatment use on six crops (barley, corn, oats, rye, sorghum, and wheat) that still remain registered and subject to reregistration.

Human Health Assessment

Toxicity

Lindane primarily affects the nervous system. In acute, subchronic, and developmental neurotoxicity studies and chronic toxicity/oncogenicity studies, lindane was found to cause neurotoxic effects. Lindane also appears to cause kidney (renal) and liver(hepatic) toxicity. In addition, there is some evidence that lindane may act as an endocrine disruptor; however, further investigation is necessary to ascertain the relevance and impact of such findings on public health.

In 2001, EPA classified lindane as having "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential" based on an increased incidence of benign lung tumors in female mice only. Therefore, pursuant to Agency cancer guidelines, cancer risks were not quantified.

Dietary Exposure

EPA assessed dietary risk by estimating exposure to lindane residues from consumption of food and drinking water that can occur over a single-day (acute) or longer (chronic). The acute and chronic dietary (food) risks are less than 100% of the acute Population Adjusted Dose for the general U.S. population and all population subgroups. Infants (<1 year) and children (1-6 years) were the most highly exposed population subgroup for acute and chronic exposure, respectively.

Because lindane persists in the environment and has long-range atmospheric transport potential, the Agency performed a supplementary chronic dietary risk assessment for the subsistence diets of indigenous peoples of the Arctic region of the U.S. (Alaska) rely heavily on game for their food source. For indigenous people of Alaska, the chronic dietary risks are generally not of concern, and although the Agency does not have information on a typical day's diet to assess acute dietary risk, limited residue data indicates that acute dietary risks are unlikely to be of concern.

Drinking water exposure to lindane can occur through ground and surface water contamination. EPA used models to conduct a screening-level assessment of potential high-end estimates of lindane concentrations in surface and ground water sources of drinking water from seed treatment uses.

Pharmaceutical Use Risk

Lindane has been approved by the FDA as a prescription drug to treat lice and scabies. EPA has conducted an assessment of these uses to determine the risk of a lice or scabies treatment. Based on the Agency's current understanding of available data, the Agency does not believe that lindane pharmaceutical products used for treatment of lice pose human health risks of concern, when used in accordance with directions provided on the label. However, based on other blood-level analyses, the Agency cannot conclude at this time with reasonable certainty that exposure to lindane through scabies treatment will not result in unacceptable exposure and risk.

Risk from All Registered Pesticide Lindane Exposures

To assess risks from all lindane exposures, the Agency combined risk from food and drinking water exposure only, because there are no registered residential or other non-occupational uses of lindane that need to be considered for regulatory purposes at this time. For the agricultural seed treatment uses of lindane, both acute and chronic estimated drinking water concentrations are below the corresponding drinking water level of comparisons (DWLOCs) for all drinking water sources, and are not of concern to the Agency.

Occupational Exposure

Occupational exposure to lindane occurs either on-farm or at commercial seed treatment facilities to farmers or workers who mix, load and/or apply lindane as a seed treatment, and persons who handle or plant treated seed. Based on the Agency's assessment, on-farm handling of the lindane dust formulation to mix/load and plant treated seed result in risks of concern. Because of the lower seed planting rate, the on-farm treatment of corn and sorghum seeds with the lindane dust formulation is permitted, provided additional personal protective equipment (PPE) is utilized. Commercial treatment of seeds with the liquid formulation for all registered uses is permitted. Also, the Agency has no risk concerns for post-application exposures to agricultural workers, and no risk mitigation measures are necessary beyond a 24-hour restricted entry interval (REI). However, provided the soil is not disturbed and there is no contact with the treated seeds, workers may enter the planted field during the 24-hour REI.

Environmental Assessment

EPA's ecological risk assessment for lindane suggests that the use of lindane can result in adverse acute and chronic effects to terrestrial organisms, and adverse acute effects to aquatic organisms. Lindane is also a potential endocrine disruptor in birds, mammals, and possibly fish.

Avian (dietary) aversion toxicity studies and a field study suggest that birds are repelled by treated seeds; hence, the Agency believes that the risk to birds by

treating certain seeds with lindane are lower and not of concern. Moreover, the Agency believes that the risks for local populations of mammals in areas where lindane treated seeds are planted are low, and that mammals may be similarly adverse to eating seeds treated with lindane. Although the assessment indicates acute risks of concerns for freshwater fish and invertebrates, and estuarine marine invertebrates, screening-level model used to assess these risks has likely produced highly conservative estimates which overestimated the environmental concentrations and resulting risks to aquatic species. Actual aquatic risks are expected to be lower and not of concern, and the Agency and is requiring data to confirm this determination.

Risk Mitigation Measures

To mitigate human health and ecological risks of concern for lindane, the following measures are to be implemented:

- On-farm treatment of wheat, barley, oats, and rye with the lindane dust formulation is prohibited;
- Maximum application rate for corn is reduced to 0.0558 lb ai/100 lb seed;
- Workers must wear double layer clothing (coveralls over long-sleeved shirt and long pants, chemical-resistant footwear), chemical-resistant gloves, and a dust/mist respirator for on-farm treatment of corn and sorghum seeds only with the dust formulation;
- A 24-hour REI is necessary for all seed treatment uses;
- All lindane end-use product labels must specify a 30-day plantback interval for leafy vegetables and a 12-month plantback interval for all other unregistered crops. The registrant may also conduct a confined accumulation of rotational crops (OPPTS 860.1850) study to show that these plantback intervals can be reduced.

Additional Data Required

EPA is requiring the submission of the following additional generic data to confirm the regulatory decision for lindane:

- OPPTS 830.1550, Product identity and description
- OPPTS 830.1620, Description of the production process
- OPPTS 830.6314, Oxidation/reduction: chemical incompatibility
- OPPTS 830.6316, Explodability
- OPPTS 830.6317, Storage stability
- OPPTS 830.6320, Corrosive characteristic
- OPPTS 830.7050, UV/Visible light absorption
- OPPTS 860.1300, Nature of residue (plant metabolism study)
- OPPTS 835.SS01, Seed leaching

Additional studies are currently reserved and may be required, pending results of the studies listed above. See the lindane RED document for further details.

The Agency also is requiring product-specific data, including product chemistry and acute toxicity studies, and revised Confidential Statements of Formula (CSFs).

Regulatory Conclusion

EPA has determined that all existing tolerances for lindane should be revoked. These tolerances are no longer necessary because all lindane products for which the tolerances were originally established have been canceled. EPA has also determined that a number of changes to the terms and conditions of registration of the seed treatment products are necessary to prevent "unreasonable adverse effects on the environment." EPA has identified additional data needed to characterize lindane metabolites in order to complete its assessment of potential dietary risks. Finally, EPA has determined that the use of lindane for seed treatment is likely to result in residues in raw agricultural commodities derived from plants grown from seeds treated with lindane. Therefore, new tolerances are required before the currently registered lindane products may be reregistered. In sum, lindane seed treatment products would be eligible for reregistration if the registrants make the changes to the registration terms and conditions specified in the RED document, provide the required data, and EPA is able to establish all required tolerances for residues of lindane in food.

EPA notes that the establishment of new tolerances for the seed treatment uses of lindane is conditioned on: 1) the receipt and review of additional data to characterize lindane metabolites; and 2) EPA's ability to make a determination that establishing the new tolerances meets the safety standard in Federal Food, Drug and Cosmetic Act (FFDCA). EPA is considering whether the statute requires the Agency to include in its safety assessment those exposures resulting from the use of lindane in pharmaceutical products.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for lindane during a 60-day public comment period, as announced in a Notice of Availability published in the Federal Register on September 25, 2002. You may access this Federal Register notice on the Internet through EPA's website at <http://www.epa.gov/fedrgstr/>.

The Federal Register notice describes how to access the RED and related documents and submit comments, including how to use EPA's electronic public docket and comment system, EPA Dockets. EPA Dockets is available on the Internet at <http://www.epa.gov/edocket/>. Electronic copies of the RED and all supporting documents related to the Agency's decision on lindane are available on the internet and can be accessed at <http://www.epa.gov/reregistration/lindane>.

Printed copies of the RED document and fact sheet are available from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the lindane RED document also will be available from the National Technical Information Service (NTIS), 5285 Port

Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the lindane RED, or reregistration of individual products containing lindane, please contact EPA's Office of Pesticide Programs, Special Review and Reregistration Division at 703-308-8000, or visit our website at <http://www.epa.gov/pesticides/>.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their Internet address is <http://npic.orst.edu>.